JUN 1 9 2001 K011137

SUMMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor:	Biomet, Inc. P.O. Box 587 Warsaw, IN 46581 –0587
Contact Person:	Sara A. Bailey Regulatory Specialist
Proprietary Name:	Resorbable Hammertoe Pin
Common or Usual Name:	Angled arthrodesis pin
Classification Name:	Screw, Fixation, Bone, Non-spinal, Non-metallic (888.3040) and Pin, Fixation, Smooth, Non-metallic (888.3040)
Device Product Code:	87HWC and HTY

Substantially Equivalent Devices: LactoSorb® Bone Pin (K953194 and K990291), ReUnite™ Screw (K992301), OrthoSorb® Absorbable Pin (K901456), Kirschner Orthopedic Wire (K850631)

Indications for Use: The Resorbable Hammertoe Pin is indicated for proximal interphalangeal (PIP) joint arthrodesis in the presence of appropriate protection or immobilization.

Device Description: The Resorbable Hammertoe Pin is made out of the Lactosorb® material and is indicated for proximal interphalangeal joint (PIP) joint arthrodesis. LactoSorb® is a polyester derivative of L-Lactic and glycolic acids. Poly L-lactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis into L-lactic and glycolic acids, which are then metabolized by the body.

The device is available with two designs, one with threads on one end and barbs on the other and one with barbs on both ends. The barbed and threaded portions of the pin have major diameters of 2.4 mm and 2.5 mm, respectively, and the overall length of the pin is 22 mm. The central portion of the pin, with a diameter of 1.9mm, is identical in geometry for both designs.

The instruments used for inserting the pins are a 2.2 mm drill tap and a 2.5 mm bone tap. Both instruments are made out of stainless steel.

Basis of Substantial Equivalence: The Resorbable Hammertoe Pin has the same intended use and material, and similar design when compared to the following bone fixation devices:

1. LactoSorb® Bone Pin, Biomet Inc., K953194 and K990291
2. ReUnite™ Screw, Biomet Inc., K992301
3. OrthoSorb® Absorbable Pin, Johnson & Johnson, K901456
4. Kirschner Orthopedic Wire, Kirschner Medical Corporation, K850631

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2001

Ms. Sara A. Bailey
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K011137
Trade Name: Resorbable Hammertoe Pin
Regulation Number: 888.3040
Regulatory Class: II
Product Code: JDW, HTY and HWC
Dated: April 12, 2001
Received: April 13, 2001

Dear Ms. Bailey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) NUMBER (IF KNOWN): K011137

DEVICE NAME: Resorbable Hammertoe Pin

INDICATIONS FOR USE:

The Resorbable Hammertoe Pin is indicated for proximal interphalangeal (PIP) joint arthrodesis in the presence of appropriate protection or immobilization.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter-Use No (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011137